



PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/601,953
Filing Date	6/24/2003
First Named Inventor	Quay
Art Unit	1614
Examiner Name	
Attorney Docket Number	02-03US

Sheet 1 of 15

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. 1	Document Number	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
ADK		US- 5,554,388	Issued 09-10-1996	Danbiosyst UK Limited	
		US- 5,629,011	Issued 05-13-1997	Danbiosyst UK Limited	
		US- 5,744,166	Issued 04-28-1998	Danbiosyst UK Limited	
		US- 5,935,604	Issued 08-10-1999	Danbiosyst UK Limited	
		US- 6,048,536	Issued 04-11-2000	Medeva Holdings BV	
		US- 6,110,747	Issued 08-29-2000	Adherex Technologies, Inc.	
		US- 6,136,606	Issued 10-24-2000	Medeva Holdings BV	
		US- 6,228,396	Issued 05-08-2001	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
ADK		US- 6,248,864	Issued 06-19-2001	Adherex Technologies, Inc.	
		US- 6,342,251	Issued 01-29-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,391,318	Issued 05-21-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre	
ADK		US- 6,383,513	Issued 05-07-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
ADK		WO 90/09780 (International Application Number PCT/GB90/00291)	09-07-1990	Danbiosyst UK Limited		
		WO 93/15737 (International Application Number PCT/GB93/00228)	08-19-1993	Danbiosyst UK Limited		
		WO 95/35100 (International Application Number PCT/GB95/01458)	12-28-1995	Danbiosyst UK Limited		
		WO 98/47535 (International Application Number PCT/GB98/01147)	10-29-1998	Danbiosyst UK Limited		
		WO 99/27905 (International Application Number PCT/GB98/03572)	06-10-1999	Danbiosyst UK Limited		
		WO 03/080021 (International Application Number PCT/GB03/01183)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
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U.S. PATENT DOCUMENTS					
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ADK		US- 6,387,917	Issued 05-14-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
ADK		US- 6,432,440	Issued 08-13-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

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ADK		WO 03/080022 (International Application Number PCT/GB03/01184)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd.		
ADK		WO 2004/062561 (International Application Number PCT/GB2004/000057)	07-29-2004	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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ADK		ARMSTRONG et al, "Clinical Modulation of Oral Leukoplakia and Protease Activity by Bowman-Birk Inhibitor Concentrate in a Phase IIa Chemoprevention Trial," <i>Clinical Cancer Research</i> , December 2000, vol. 6 no. 12, pages 4684-4691.	
		TOMEE et al, "Secretory leukoprotease inhibitor: a native antimicrobial protein presenting a new therapeutic option?" <i>Thorax</i> , February 1998, vol. 53 no. 2, pages 114-116.	
		TOMEE et al, "Antileukoprotease: An Endogenous Protein in the Innate Mucosal Defense against Fungi," <i>The Journal of Infectious Diseases</i> , September 1997, vol. 176 no. 3, pages 740-747.	
		RAO et al, "Interaction of Secretory Leukocyte Protease Inhibitor with Proteinase-3," <i>American Journal of Respiratory Cell and Molecular Biology</i> , June 1993, vol. 8 no. 6, pages 612-616.	
		THOMSON and OHLSSON, "Isolation, properties, and complete amino acid sequence of human secretory leukocyte protease inhibitor, a potent inhibitor of leukocyte elastase," <i>Proc. Natl. Acad. Sci. USA</i> , September 1986, vol. 83 no. 18, pages 6692-6696.	
		FARRAJ et al, "Nasal Administration of Insulin Using Bioadhesive Microspheres as a Delivery System," <i>Journal of Controlled Release</i> , 1990, vol. 13, pages 253-261, Elsevier Science Publishers B.V., Amsterdam.	
		ILLUM et al, "Chitosan as a Novel Nasal Delivery System for Peptide Drugs," <i>Pharmaceutical Research</i> , 1994, vol. 11 no. 8, pages 1186-1189, Plenum Publishing Corporation.	
		COYNE et al, "Enhanced Epithelial Gene Transfer by Modulation of Tight Junctions with Sodium Caprate," <i>American Journal of Respiratory Cell and Molecular Biology</i> , November 2000, vol. 23, pages 602-609, High Wire Press.	
		FERRUZA et al, "Copper treatment alters the permeability of tight junctions in cultured human intestinal Caco-2 cells," <i>American Journal of Physiology</i> , December 1999, 277 (6 Pt 1): G1138-1148.	
		LIU et al, "Dodecylphosphocholine-Mediated Enhancement of Paracellular Permeability and Cytotoxicity in Caco-2 Cell Monolayers," <i>Journal of Pharmaceutical Sciences</i> , November 1999, vol. 88, no. 11, pages 1161-1168.	
ADK		KARLSSON et al, "Paracellular drug transport across intestinal epithelia: influence of charge and induced water flux," <i>European Journal of Pharmaceutical Sciences</i> , October 1999, vol. 9, no. 1, pages 47-56.	

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		<b>Filing Date</b>	6/24/2003
		<b>First Named Inventor</b>	Quay
		<b>Art Unit</b>	1614
		<b>Examiner Name</b>	
(Use as many sheets as necessary)		<b>Attorney Docket Number</b>	02-03US
Sheet	4	of	15

NON PATENT LITERATURE DOCUMENTS			
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ADK		DUIZER et al, "Absorption Enhancement, Structural Changes in Tight Junctions and Cytotoxicity Caused by Palmitoyl Carnitine in Caco-2 and IEC-18 Cells," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , October 1998, vol. 287, no. 1, pages 395-402.	
		BREWSTER et al, "The Effect of Dihydronicotinate N-Substitution on the Brain-Targeting Efficacy of a Zidovudine Chemical Delivery System," <i>Pharmaceutical Research</i> , 1993, vol. 10, no. 9, pages 1356-1362.	
		DREJER et al, "Intranasal Administration of Insulin With Phospholipid as Absorption Enhancer: Pharmacokinetics in Normal Subjects," <i>Diabetic Medicine</i> , 1992, vol. 9, pages 335-340.	
		FISHER et al, "Effect of L- $\alpha$ -lysophosphatidylcholine on the nasal absorption of human growth hormone in three animal species," <i>International Journal of Pharmaceutics</i> , 1991, vol. 74, pages 147-156, Elsevier Science Publishers B.V.	
		HALMOS et al, "Synthesis of O-methylsulfonyl derivatives of D-glucose as potential alkylating agents for targeted drug delivery to the brain. Evaluation of their interaction with the human erythrocyte GLUT1 hexose transporter," <i>Carbohydrate Research</i> , 1997, vol. 299, pages 15-21, Elsevier.	
		HOCHMAN and ARTURSSON, "Mechanisms of absorption enhancement and tight junction regulation," <i>Journal of Controlled Release</i> , 1994, vol. 29, pages 253-267.	
		JACOBS et al, "The Pharmacodynamics and Activity of Intranasally Administered Insulin in Healthy Male Volunteers," <i>Diabetes</i> , November 1993, vol. 42, pages 1649-1655.	
		NEGRI et al, "Glycodermorphins: opioid peptides with potent and prolonged analgesic activity and enhanced blood-brain barrier penetration," <i>British Journal of Pharmacology</i> , 1998, vol. 124, pages 1516-1522, Stockton Press.	
		PARDRIDGE, "New approach to drug delivery through the blood-brain barrier," <i>Trends in Biotechnology</i> , 1994, vol. 12, pages 239-245, Elsevier Science Ltd., Cambridge, UK.	
		POLT et al, "Glycopeptide enkephalin analogues produce analgesia in mice: Evidence for penetration of the blood-brain barrier," <i>Proc. Natl. Acad. Sci. USA</i> , July 1994, vol. 91, pages 7114-7118, Pharmacology.	
ADK		TAMAI et al, "Structure-Internalization Relationship for Adsorptive-Mediated Endocytosis of Basic Peptides at the Blood-Brain Barrier," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 1997, vol. 280, no. 1, pages 410-415.	

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ADK		TSUZUKI et al, "Adamantane as a Brain-Directed Drug Carrier for Poorly Absorbed Drug. 2. AZT Derivatives Conjugated with the 1-Adamantane Moiety," <i>Journal of Pharmaceutical Sciences</i> , April 1994, vol. 83, no. 4, pages 481-484.	
		WAKAMIYA et al, "Design and Synthesis of Peptides Passing through the Blood-Brain Barrier," <i>Bull. Chem. Soc. Jpn.</i> , 1998, vol. 71, pages 699-709.	
		THANOU et al, "Intestinal Absorption of Octreotide: N-Trimethyl Chitosan Chloride (TMC) Ameliorates the Permeability and Absorption Properties of the Somatostatin Analogue <i>In vitro</i> and <i>In vivo</i> ," <i>Journal of Pharmaceutical Sciences</i> , July 2000, vol. 89, no. 7, pages 951-957.	
		TAMAI and TSUJI, "Transporter-Mediated Permeation of Drugs Across the Blood-Brain Barrier," <i>Journal of Pharmaceutical Sciences</i> , November 2000, vol. 89, no. 11, pages 1371-1388.	
		ABBOTT, "Inflammatory Mediators and Modulation of Blood-Brain Barrier Permeability," <i>Cellular and Molecular Neurobiology</i> , April 2000, vol. 20, no. 2, pages 131-147, Plenum Publishing Corporation.	
		UCHIMAYA et al, "Enhanced Permeability of Insulin across the Rat Intestinal Membrane by Various Absorption Enhancers: Their Intestinal Mucosal Toxicity and Absorption-enhancing Mechanism of n-Lauryl-β-D-maltopyranoside," <i>J. Pharm. Pharmacol.</i> , November 1999, vol. 51, no. 11, pages 1241-1250.	
		LIU et al, "Structure-Activity Relationships for Enhancement of Paracellular Permeability by 2-Alkoxy-3-alkylamidopropylphosphocholines across Caco-2 Cell Monolayers," <i>Journal of Pharmaceutical Sciences</i> , November 1999, vol. 88, no. 11, pages 1169-1174.	
		FASANO, "Modulation of Intestinal Permeability: An Innovative Method of Oral Drug Delivery for the Treatment of Inherited and Acquired Human Diseases," <i>Molecular Genetics and Metabolism</i> , May 1998, vol. 64, pages 12-18, Academic Press.	
		FASANO and UZZAU, "Modulation of Intestinal Tight Junctions by Zonula Occludens Toxin Permits Enteral Administration of Insulin and Other Macromolecules in an Animal Model," <i>J. Clin. Invest.</i> , March 1997, vol. 99, no. 6, pages 1158-1164.	
		ANDERBERG et al, "Sodium Caprate Elicits Dilations in Human Intestinal Tight Junctions and Enhances Drug Absorption by the Paracellular Route," <i>Pharmaceutical Research</i> , 1993, vol. 10, no. 6, pages 857-864, Plenum Publishing Corporation.	
		CREMASCHI et al, "Endocytosis of Polypeptides in Rabbit Nasal Respiratory Mucosa," <i>News Physiol. Sci.</i> , October 1997, vol. 12, pages 219-225.	
ADK		HIRAI et al, "Mechanisms for the enhancement of the nasal absorption of insulin by surfactants," <i>International Journal of Pharmaceuticals</i> , 1981, vol. 9, pages 173-184, Elsevier/North-Holland Biomedical Press.	

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		LEE et al, "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1991, vol. 8, no. 2, pages 91-192, CRC Press, Inc.		
		MISHIMA et al, "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats," <i>J. Pharmacobio-Dyn.</i> , 1987, vol. 10, pages 624-631.		
		NAGAI et al, "Powder Dosage Form of Insulin for Nasal Administration," <i>Journal of Controlled Release</i> , 1984, vol. 1, pages 15-22, Elsevier Science Publishers B.V., Amsterdam, The Netherlands.		
		ROJANASAKUL et al, "The Transport Barrier of Epithelia: A Comparative Study on Membrane Permeability and Charge Selectivity in the Rabbit," <i>Pharmaceutical Research</i> , 1992, vol. 9, no. 8, pages 1029-1034, Plenum Publishing Corporation.		
		RYDÉN and EDMAN, "Effect of polymers and microspheres on the nasal absorption of insulin in rats," <i>International Journal of Pharmaceutics</i> , 1992, vol. 83, pages 1-10, Elsevier Science Publishers B.V.		
		SHEN et al, "Calu-3: a human airway epithelial cell line that shows cAMP-dependent Cl <sup>-</sup> secretion," <i>Am. J. Physiol.</i> , May 1994, vol. 266, no. 5 pt. 1, pages L493-501.		
		UCHIMAYA et al, "Effectiveness and Toxicity Screening of Various Absorption Enhancers in the Large Intestine: Intestinal Absorption of Phenol Red and Protein and Phospholipid Release from the Intestinal Membrane," <i>Biol. Pharm. Bull.</i> , 1996, vol. 19, no. 12, pages 1618-1621.		
		UCHIMAYA et al, "Effects of Various Protease Inhibitors on the Stability and Permeability of [D-Ala <sup>2</sup> , D-Leu <sup>5</sup> ]enkephalin in the Rat Intestine: Comparison with Leucine Enkephalin," <i>Journal of Pharmaceutical Sciences</i> , April 1998, vol. 87, no. 4, pages 448-452.		
		UTOGUCHI et al, "Nitric Oxide Donors Enhance Rectal Absorption of Macromolecules in Rabbits," <i>Pharmaceutical Research</i> , 1998, vol. 15, no. 6, pages 870-876, Plenum Publishing Corporation.		
		WATANABE et al, "Enhancing Effect of Cyclodextrins on Nasal Absorption of Insulin and Its Duration in Rabbits," <i>Chem. Pharm. Bull.</i> , 1992, vol. 40, no. 11, pages 3100-3104.		
ADK		YAMAMOTO et al, "Effectiveness and Toxicity Screening of Various Absorption Enhancers in the Rat Small Intestine: Effects of Absorption Enhancers on the Intestinal Absorption of Phenol Red and the Release of Protein and Phospholipids from the Intestinal Membrane," <i>J. Pharm. Pharmacol.</i> , 1996, vol. 48, pages 1285-1289.		

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ADK		DREISIN and MOSTOW, "Sulfhydryl-mediated depression of ciliary activity: an adverse effect of acetylcysteine," <i>J. Lab. Clin. Med.</i> , April 1979, vol. 93, no. 4, pages 674-678.		
		DAVIES, "Biopharmaceutical Considerations in Topical Ocular Drug Delivery," <i>Clinical and Experimental Pharmacology and Physiology</i> , July 2000, vol. 27, no. 7, pages 558-562.		
		TORRES-LUGO and PEPPAS, "Transmucosal delivery systems for calcitonin: a review," <i>Biomaterials</i> , June 2000, vol. 21, no. 12, pages 1191-1196, Elsevier.		
		LIM et al, "Preparation and evaluation of the in vitro drug release properties and mucoadhesion of novel microspheres of hyaluronic acid and chitosan," <i>Journal of Controlled Release</i> , May 2000, vol. 66, no. 2-3, pages 281-292, Elsevier.		
		HUANG et al, "Molecular aspects of muco- and bioadhesion: Tethered structures and site-specific surfaces," <i>Journal of Controlled Release</i> , March 2000, vol. 65, no. 1-2, pages 63-71, Elsevier.		
		SUGIMOTO et al, "Evaluation of Poly(vinyl alcohol)-Gel Spheres Containing Chitosan as Dosage Form to Control Gastrointestinal Transit Time of Drugs," <i>Biol. Pharm. Bull.</i> , vol. 21, no. 11, pages 1202-1206.		
		WATANABE et al, "Studies of Drug Delivery Systems for a Therapeutic Agent Used in Osteoporosis. II. <sup>1)</sup> Enhanced Absorption of Elcatonin from Nasal Mucosa in Rabbits <sup>2)</sup> ," November 1998, <i>Biol. Pharm. Bull.</i> , vol. 21, no. 11, pages 1191-1194.		
		NIELSEN et al, "Bioadhesive drug delivery systems I. Characterization of mucoadhesive properties of systems based on glyceryl monolinoleate," <i>European Journal of Pharmaceutical Sciences</i> , July 1998, vol. 6, no. 3, pages 231-239, Elsevier.		
		NAIR et al, "Biomembrane Permeation of Nicotine: Mechanistic Studies with Porcine Mucosae and Skin," <i>Journal of Pharmaceutical Sciences</i> , February 1997, vol. 86, no. 2, pages 257-262.		
		BHAT et al, "Drug Diffusion through Cystic Fibrotic Mucus: Steady-State Permeation, Rheologic Properties, and Glycoprotein Morphology," <i>Journal of Pharmaceutical Sciences</i> , June 1996, vol. 85, no. 6, pages 624-630.		
		LEHR, "From sticky stuff to sweet receptors - achievements, limits and novel approaches to bioadhesion," <i>European Journal of Drug Metabolism and Pharmacokinetics</i> , April-June 1996, vol. 21, no. 2, pages 139-148.		
ADK		HARRIS and ROBINSON, "Drug Delivery via the Mucous Membranes of the Oral Cavity," <i>Journal of Pharmaceutical Sciences</i> , January 1992, vol. 81, no. 1, pages 1-10.		

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ADK		CORBO et al, "Drug Absorption Through Mucosal Membranes: Effect of Mucosal Route and Penetrant Hydrophilicity," <i>Pharmaceutical Research</i> , October 1989, vol. 6, no. 10, pages 848-852.	
		CORBO et al, "Characterization of the Barrier Properties of Mucosal Membranes," <i>Journal of Pharmaceutical Sciences</i> , March 1990, vol. 79, no. 3, pages 202-206.	
		WILSON et al, "Applications of Endocytosis Research to Drug Delivery," <i>Prog. Clin. Biol. Res.</i> , 1988, vol. 270, pages 441-446.	
		DRAGHIA et al, "Gene delivery into the central nervous system by nasal installation in rats," <i>Gene Therapy</i> , 1995, vol. 2, pages 418-423, Stockton Press.	
		SAKANE et al, "Direct drug transport from the rat nasal cavity to the cerebrospinal fluid: the relation to the dissociation of the drug," <i>J. Pharm. Pharmacol.</i> , 1994, vol. 46, pages 378-379.	
		SAKANE et al, "Direct Drug Transport from the Rat Nasal Cavity to the Cerebrospinal Fluid: the Relation to the Molecular Weight of Drugs," <i>J. Pharm. Pharmacol.</i> , 1995, vol. 47, pages 379-381.	
		SEKI et al, "Nasal Absorption of Zidovudine and Its Transport to Cerebrospinal Fluid," <i>Biol. Pharm. Bull.</i> , August 1994, vol. 17, no. 8, 1135-1137.	
		THORNE et al, "Quantitative analysis of the olfactory pathway for drug delivery to the brain," <i>Brain Research</i> , 1995, vol. 692, pages 278-282, Elsevier Science B.V.	
		VAWTER et al, "Human Olfactory Neuroepithelial Cells: Tyrosine Phosphorylation and Process Extension Are Increased by the Combination of IL-1 $\beta$ , IL-6, NGF, and bFGF," <i>Experimental Neurology</i> , 1996, vol. 142, pages 179-194 (Article no. 0189).	
		BOADO et al, "Drug Delivery of Antisense Molecules to the Brain for Treatment of Alzheimer's Disease and Cerebral AIDS," <i>Journal of Pharmaceutical Sciences</i> , November 1998, vol. 87, no. 11, pages 1308-1315.	
		ELBERT et al, "Monolayers fo Human Alveolar Epithelial Cells In Primary Culture for Pulmonary Absorption and Transport Studies," <i>Pharmaceutical Research</i> , May 1999, vol. 16, no. 5, pages 601-608.	
		SALARTASH et al, "Oral low-molecular weight heparin and delivery agent prevents jugular venous thrombosis in the rat," <i>J. Vasc. Surg.</i> , September 1999, vol. 30, no. 3, pages 526-531.	
ADK		BERNKOP-SCHNÜRCH et al, "Peroral Polypeptide Delivery," <i>Arzneimittelforschung</i> , September 1999, vol. 49, no. 9, pages 799-803.	

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ADK		LEWIS et al, "PMA alters folate receptor distribution in the plasma membrane and increases the rate of 5-methyltetrahydrofolate delivery in mature MA104 cells," <i>Biochimica et Biophysica Acta</i> , 1998, vol. 1401, pages 157-169.		
		LUKACS et al, "Constitutive Internalization of cystic fibrosis transmembrane conductance regulator occurs via clathrin-dependent endocytosis and is regulated by protein phosphorylation," <i>Biochem J.</i> , December 1997, vol. 328, pages 353-361.		
		ADSON et al, "Quantitative Approaches to Delineate Paracellular Diffusion in Cultured Epithelial Cell Monolayers," <i>Journal of Pharmaceutical Sciences</i> , November 1994, vol. 83, no. 11, pages 1529-1536.		
		ADSON et al, "Passive Diffusion of Weak Organic Electrolytes across Caco-2 Cell Monolayers: Uncoupling the Contributions of Hydrodynamic, Transcellular, and Paracellular Barriers," <i>Journal of Pharmaceutical Sciences</i> , October 1995, vol. 84, no. 10, pages 1197-1204.		
		BALBONI et al, "Immunohistochemical Detection of EGF and NGF Receptors in Human Olfactory Epithelium," <i>Boll. Soc. It. Biol. Sper.</i> , 1991, no. 10/11, vol. LXVII, Idelson, Naples, Italy.		
		DECKNER et al, "Localization of neurotrophin receptors in olfactory epithelium and bulb," <i>NeuroReport</i> , December 1993, vol. 5, no. 3, pages 301-304.		
		FERKOL et al, "Gene Transfer into Respiratory Epithelial Cells by Targeting the Polymeric Immunoglobulin Receptor," <i>J. Clin. Invest.</i> , November 1993, vol. 92, pages 2394-2400.		
		LAMAZE and SCHMID, "The emergence of clathrin-independent pinocytic pathways," <i>Current Opinion in Cell Biology</i> , 1995, vol. 7, pages 573-580.		
		LANGER, "Selected advances in drug delivery and tissue engineering," <i>Journal of Controlled Release</i> , November 1999, vol. 62, no. 1-2, pages 7-11, Elsevier Science B.V.		
		HUTER et al, "Bacterial ghosts as drug carrier and targeting vehicles," <i>Journal of Controlled Release</i> , August 1999, vol. 61, no. 1-2, pages 51-63, Elsevier Science B.V.		
		REDDY and LOW, "Folate-Mediated Targeting of Therapeutic and Imaging Agents to Cancers," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1998, vol. 15, no. 6, pages 587-627.		
ADK		HOLLADAY et al, "Riboflavin-mediated delivery of a macromolecule into cultured human cells," <i>Biochimica et Biophysica Acta</i> , January 1999, vol. 1426, no. 1, pages 195-204, Elsevier Science B.V.		

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		SWAAN, "Recent Advances in Intestinal Macromolecular Drug Delivery via Receptor-Mediated Transport Pathways," <i>Pharmaceutical Research</i> , June 1998, vol. 15, no. 6, pages 826-834, Plenum Publishing Corporation.		
		HOPE et al, "Cationic lipids, phosphatidylethanolamine and the intracellular delivery of polymeric, nucleic acid-based drugs (Review)," <i>Molecular Membrane Biology</i> , January-March 1998, vol. 15, no. 1, pages 1-14.		
		KONIGSBERG et al, "The development of IL-2 conjugated liposomes for therapeutic purposes," <i>Biochimica et Biophysica Acta</i> , March 1998, vol. 1370, no. 2, pages 243-251, Elsevier Science B.V.		
		WU et al, "Development of a Novel Drug-Delivery System Using Bacterio-Phage MS2 Capsids," <i>Biochemical Society Transactions</i> , August 1996, vol. 24, no. 3, page 413S.		
		NOMURA et al, "Effect of Histamine on the Blood-Tumor Barrier in Transplanted Rat Brain Tumors," <i>Acta Neurochir</i> , 1994, vol. 60, pages 400-402.		
		KIRSTEN et al, "Clinical Pharmacokinetics of Vasodilators," <i>Clin. Pharmacokinet.</i> , June 1998, vol. 34, no. 6, pages 457-462.		
		WAXMAN et al, "Persistent Primary Coronary Dilation Induced by Transatrial Delivery of Nitroglycerin Into the Pericardial Space: A Novel Approach for Local Cardiac Drug Delivery," <i>Journal of the American College of Cardiology</i> , June 1999, vol. 33, no. 7, pages 2073-2077, Elsevier Science Inc.		
		CORNFIELD et al, "Aerosol delivery of diethylenetriamine/nitric oxide, a nitric oxide adduct, causes selective pulmonary vasodilation in perinatal lambs," <i>J. Lab. Clin. Med.</i> , October 1999, vol. 134, no. 4, pages 419-425.		
		PUTENSEN et al, "Cardiopulmonary Effects of Aerosolized Prostaglandin E <sub>1</sub> and Nitric Oxide Inhalation in Patients with Acute Respiratory Distress Syndrome," <i>Am. J. Respir. crit. Care Med.</i> , June 1998, vol. 157, no. 6 Pt 1, pages 1743-1747.		
		KATO and SUGIYAMA, "Targeted Delivery of Peptides, Proteins, and Genes by Receptor-Mediated Endocytosis," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1997, vol. 14, no. 3, pages 287-331.		
ADK		TAKAHASHI et al, "The Enhancing Mechanism of Capric Acid (C10) from a Suppository on Rectal Drug Absorption through a Paracellular Pathway," <i>Biol. Pharm. Bull.</i> , 1994, vol. 20, no. 4, pages 446-448.		

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		BOEK et al, "Physiologic and Hypertonic Saline Solutions Impair Ciliary Activity in Vitro," <i>Laryngoscope</i> , March 1999, vol. 109, no. 3; pages 396-399, Lippincott Williams & Wilkins, Inc., Philadelphia.		
		KARTTUNEN et al, "The Effects of Vagocaine, Dextromethorphan, Diphenhydramine, and Hydroxyzine on the Ciliary Beat Frequency in Rats <i>in Vitro</i> ," <i>Pharmacology &amp; Toxicology</i> , August 1990, vol. 62, no. 2, pages 159-161.		
		HERMENS et al, "Effects of Absorption Enhancers on Human Nasal Tissue Ciliary Movement <i>In Vitro</i> ," <i>Pharmaceutical Research</i> , February 1990, vol. 7, no. 2, pages 144-146.		
		CHIEN, <i>Transnasal Systemic Medications. Fundamentals, Developmental Concepts and Biomedical Assessments</i> , 1985, Elsevier Science, Amsterdam.		
		EPPSTEIN and LONGENECKER, "Alternative Delivery Systems for Peptides and Proteins as Drugs," <i>CRC Crit. Rev. Ther. Drug Carrier Syst.</i> , 1988, vol. 5, issue 2, pages 99-139.		
		LONGENECKER et al, "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep," <i>Journal of Pharmaceutical Science</i> , 1987, vol. 76, pages 351-355.		
		BOEK et al, "Validation of Animal Experiments on Ciliary Function <i>In Vitro</i> . I. The Influence of Substances Used Clinically," <i>Acta Otolaryngol</i> , January 1999, vol. 119, no. 1, pages 93-97, Scandinavian University Press, Stockholm.		
		HINGLEY et al, "Effect of Ciliostatic Factors from <i>Pseudomonas aeruginosa</i> on Rabbit Respiratory Cilia," <i>Infection and Immunity</i> , January 1986, vol. 51, no. 1, pages 254-262.		
		GABRIDGE et al, "Effects of Heavy Metals on Structure, Function, and Metabolism of Ciliated Respiratory Epithelium <i>In Vitro</i> ," <i>In Vitro</i> , December 1982, vol. 18, no. 12, pages 1023-1032.		
		YAMAMOTO et al, "Modulation of Intestinal Permeability by Nitric Oxide Donors: Implications in Intestinal Delivery of Poorly Absorbable Drugs," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 2001, vol. 296, no. 1, pages 84-90.		
ADK		HENRIKSSON et al, "Calculation of the isoelectric points of native proteins with spreading of pK <sub>a</sub> values," <i>Electrophoresis</i> , vol. 16, no. 8, pages 1377-1380.		

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		PADE and STAVCHANSKY, "Estimation of the Relative Contribution of the Transcellular and Paracellular Pathway to the Transport of Passively Absorbed Drugs in the Caco-2 Cell Culture Model," <i>Pharmaceutical Research</i> , September 1997, vol. 14, no. 9, pages 1210-1215, Plenum Publishing Company.	
		MURAKAMI et al, "Role of the Dispersion Systems Containing Fusogenic Lipids on the Enhanced Absorption of Poorly Absorbable Drugs from the Gastrointestinal Tract," <i>Journal of Pharmacobio-Dyn.</i> , 1985, vol. 8, s-131, page 49.	
		MURANISHI, "Absorption Enhancers," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 1990, vol. 7, issue 1, pages 1-33.	
		TOZAKI et al, "Enhanced Absorption of Insulin and (Asu <sup>1,7</sup> )Eel-Calcitonin using Novel Azopolymer-Coated Pellets for Colon-Specific Drug Delivery," <i>Journal of Pharmaceutical Sciences</i> , January 2001, vol. 90, no. 1, pages 89-97.	
		SENEL et al, "Enhancing effect of chitosan on peptide drug delivery across buccal mucosa," <i>Biomaterials</i> , October 2000, vol. 21, no. 20, pages 2067-2071, Elsevier Science Ltd.	
		MARSCHÜTZ and BERNKOP-SCHNÜRCH, "Oral peptide drug delivery: polymer-inhibitor conjugates protecting insulin from enzymatic degradation in vitro," <i>Biomaterials</i> , July 2000, vol. 21, no. 14, pages 1499-1507.	
		BERNKOP-SCHNÜRCH and THALER, "Polycarbophil-Cysteine Conjugates as Platforms for Oral Polypeptide Delivery Systems," <i>Journal of Pharmaceutical Sciences</i> , July 2000, vol. 89, no. 7, pages 901-909.	
		ALI et al, "Transferrin Trojan Horses as a Rational Approach for the Biological Delivery of Therapeutic Peptide Domains," <i>The Journal of Biological Chemistry</i> , August 1999, vol. 274, no. 34, pages 24066-24073.	
		BERNKOP-SCHNÜRCH, "The use of inhibitory agents to overcome the enzymatic barrier to perorally administered therapeutic peptides and proteins," <i>Journal of Controlled Release</i> , March 1998, vol. 52, no. 1-2, pages 1-16, Elsevier Science B.V.	
		KRATZEL et al, "Auxiliary Agents for the Peroral Administration of Peptide and Protein Drugs: Synthesis and Evaluation of Novel Pepstatin Analogues," <i>J. Med. Chem.</i> , June 1998, vol. 41, no. 13, pages 2339-2344.	
ADK		BAI et al, "Effects of Polyacrylic Polymers on the Degradation of Insulin and Peptide Drugs by Chymotrypsin and Trypsin," <i>J. Pharm. Pharmacol.</i> , January 1996, vol. 48, no. 1, pages 17-21.	

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		<i>First Named Inventor</i>	Quay
		<i>Art Unit</i>	1614
		<i>Examiner Name</i>	
(Use as many sheets as necessary)		<i>Attorney Docket Number</i>	02-03US
Sheet	13	of	15

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ADK		EKRAMI et al, "Disposition of Positively Charged Bowman-Birk Protease Inhibitor Conjugates in Mice: Influence of Protein Conjugate Charge Density and Size on Lung Targeting," <i>Journal of Pharmaceutical Sciences</i> , April 1995, vol. 84, no. 4, pages 456-461.	
		MARSTON and HARTLEY, "Solubilization of Protein Aggregates," <i>Methods in Enzymology</i> , vol. 182, no. 1, pages 264-276.	
		DAUGHERTY and GELLMAN, "A Fluorescence Assay for Leucine Zipper Dimerization: Avoiding Unintended Consequences of Fluorophore Attachment," <i>J. Am. Chem. Soc.</i> , 1999, vol. 121, pages 4325-4333.	
		FAN et al, "Inhibition of HIV-1 Protease by a Submit of Didemnaketel A," <i>J. Am. Chem. Soc.</i> , 1998, vol. 120, pages 8893-8894.	
		GAMBONI et al, "Inhibition of the cAMP-Dependent Protein Kinase by Synthetic A-Helix Peptides," <i>Biochemistry</i> , 1998, vol. 37, pages 12189-12194.	
		GHOSH and CHMIELEWSKI, "A $\beta$ -sheet peptide inhibitor of E47 dimerization and DNA binding," <i>Chem. Biol.</i> , August 1998, vol. 5, pages 439-445.	
		JUDICE et al, "Inhibition of HIV type 1 infectivity by constrained $\alpha$ -helical peptides: Implications for the viral fusion mechanism," <i>Proc. Natl. Acad. Sci.</i> , December 1997, vol. 94, pages 13426-13430.	
		PARK et al, "Protein Surface Recognition by Synthetic Receptors: A Route to Novel Submicromolar Inhibitors for $\alpha$ -Chymotrypsin," <i>J. Am. Chem. Soc.</i> , 1999, vol. 121, pages 8-13.	
		ZUTSHI et al, "Targeting the Dimerization Interface of HIV-1 Protease: Inhibition with Cross-Linked Interfacial Peptides," <i>J. Am. Chem. Soc.</i> , 1997, vol. 119, pages 4841-4845.	
		NAM et al, "Lysozyme Microencapsulation Within Biodegradable PLGA Microspheres: Urea Effect on Protein Release and Stability," <i>Biotechnol. Bioeng.</i> , November 2000, vol. 70, no. 3, pages 270-277.	
		LEUNG et al, "Selective disruption of protein aggregation by cyclodextrin dimers," <i>Proc Natl. Acad. Sci.</i> , May 2000, vol. 97, no. 10, pages 5050-5053.	
		NAGAI et al, "Inhibition of Polyglutamine Protein Aggregation and Cell Death by Novel Peptides Identified by Phage Display Screening," <i>The Journal of Biological Chemistry</i> , April 2000, vol. 275, no. 14, pages 10437-10442.	
ADK		BROGLIA et al, "Folding and aggregation of designed proteins," <i>Proc. Natl. Acad. Sci.</i> , October 1998, vol. 95, no. 22, pages 12930-12933.	

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ADK		KHAN et al, "Solubilization of Recombinant Ovine Growth Hormone with Retention of Native-like Secondary Structure and Its Refolding from the Inclusion Bodies of <i>Escherichia coli</i> ," <i>Biotechnol. Prog.</i> , September-October 1997, vol. 14, no. 5, pages 722-728.	
		KENDRICK et al, "Aggregation of Recombinant Human Interferon Gamma: Kinetics and Structural Transitions," <i>Journal of Pharmaceutical Sciences</i> , September 1998, vol. 87, no. 9, pages 1069-1076.	
		KOPITO, "Aggresomes, inclusion bodies and protein aggregation," <i>Trends in Cell Biology</i> , December 2000, vol. 10, no. 12, pages 524-530.	
		FUTAKI et al, "Arginine-rich Peptides. An Abundant Source of Membrane-Permeable Peptides Having Potential as Carriers for Intracellular Protein Delivery," <i>The Journal of Biological Chemistry</i> , February 2001, vol. 276, no. 8, pages 5836-5840.	
		LAI et al, "Intercellular delivery of a herpes simplex virus VP22 fusion protein from cells infected with lentiviral vectors," <i>Proc. Natl. Acad. Sci. USA</i> , October 2000, vol. 97, no. 21, pages 11297-11302.	
		MEYENBURG et al, "Fibrin encapsulated liposomes as protein delivery system Studies on the in vitro release behavior," <i>Journal of Controlled Release</i> , October 2000, vol. 69, no. 1, pages 159-168, Elsevier Science B.V.	
		TOBÍO et al, "The role of PEG on the stability in digestive fluids and in vivo fate of PEG-PLA nanoparticles following oral administration," <i>Colloids and Surfaces B: Biointerfaces</i> , October 2000, vol. 18, no. 3-4, pages 315-323.	
		BEZEMER et al, "Microspheres for protein delivery prepared from amphiphilic multiblock copolymers. 1. Influence of preparation techniques on particle characteristics and protein delivery," <i>Journal of Controlled Release</i> , July 2000, vol. 67, no. 2-3, pages 233-248, Elsevier Science B.V.	
		BEZEMER et al, "Microspheres for protein delivery prepared from amphiphilic multiblock copolymers. 2. Modulation of release rate," <i>Journal of Controlled Release</i> , July 2000, vol. 67, no. 2-3, pages 249-260, Elsevier Science B.V.	
		GUILLAUME et al, "Phosphonocationic Lipids in Protein Delivery to Mice Lungs," <i>Journal of Pharmaceutical Sciences</i> , May 2000, vol. 89, no. 5, pages 639-645.	
		GALÁN and COLLMER, "Type III Secretion Machines: Bacterial Devices for Protein Delivery into Host Cells," <i>Science</i> , May 1999, vol. 284, no. 5418, pages 1322-1328.	
ADK		WITSCHI and MRSNY, "In Vitro Evaluation of Microparticles and Polymer Gels for Use as Nasal Platforms for Protein Delivery," <i>Pharmaceutical Research</i> , March 1999, vol. 16, no. 3, pages 382-390.	

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		COOMBES et al, "The control of protein release from poly( $\alpha$ -lactide co-glycolide) microparticles by variation of the external aqueous phase surfactant in the water-in oil-in water method," <i>Journal of Controlled Release</i> , March 1998, vol. 52, pages 311-320.	
		BERNKOP-SCHNÜRCH and PASTA, "Intestinal Peptide and Protein Delivery: Novel Bioadhesive Drug-Carrier Matrix Shielding from Enzymatic Attack," <i>Journal of Pharmaceutical Sciences</i> , April 1998, vol. 87, no. 4, pages 430-434.	
		CHIBA et al, "Controlled protein delivery from biodegradable tyrosine-containing poly(anhydride-co-imide) microspheres," <i>Biomaterials</i> , July 1997, vol. 18, no. 13, pages 893-901.	
		MOY et al, "Tat-Mediated Protein Delivery Can Facilitate MHC Class I Presentation of Antigens," <i>Molecular Biotechnology</i> , October 1996, vol. 6, no. 2, pages 105-113.	
		CEVC, "Transfersomes, Liposomes and Other Lipid Suspensions on the Skin: Permeation Enhancement, Vesicle Penetration, and Transdermal Drug Delivery," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1996, vol. 13, no. 3-4, pages 257-388.	
		KUO and SALTZMAN, "Novel Systems for Controlled Delivery of Macromolecules," <i>Critical Reviews in Eukaryotic Gene Expression</i> , 1996, vol. 6, no. 1, pages 59-73.	
ADK		AURRAND-LIONS, M.; DUNCAN, L.; BALLESTREM, C.; and IMHOF, B. A.; "JAM-2, a Novel Immunoglobulin Superfamily Molecule, Expressed by Endothelial and Lymphatic Cells;" <i>J Biol Chem</i> ; January 2001; 276 (4); 2733-2741	

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